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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,676	10/17/2005	Maryam Asfari	MERCK-3082	1847
23599 7590 06/29/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER VIVLEMORE, TRACY ANN	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 06/29/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/553,676

Applicant(s)

ASFARI ET AL.

Examiner

Tracy Vivlemore

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 and 2, drawn to use of a modulator of the expression or activity of the E21G4 gene for the manufacture of a drug for the treatment of diabetes or its complications, obesity or insulin resistance wherein the modulator is an activator of the activity of the E21G4 protein.

Group 2, claim(s) 1 and 3, drawn to use of a modulator of the expression or activity of the E21G4 gene for the manufacture of a drug for the treatment of diabetes or its complications, obesity or insulin resistance wherein the modulator is an inducer of the expression of the E21G4 gene.

Group 3, claim(s) 1, 4 and 5, drawn to use of a modulator of the expression or activity of the E21G4 gene for the manufacture of a drug for the treatment of diabetes or its complications, obesity or insulin resistance wherein the modulator is an inhibitor of the activity of the E21G4 protein.

Group 4, claim(s) 1 and 6-8, drawn to use of a modulator of the expression or activity of the E21G4 gene for the manufacture of a drug for the treatment of diabetes or its complications, obesity or insulin resistance wherein the modulator is a repressor of the expression of the E21G4 gene.

Group 5, claim(s) 9 and 10, drawn to a pharmaceutical composition comprising the E21G4 protein.

Group 6, claim(s) 11 and 12, drawn to a pharmaceutical composition comprising a nucleic acid coding for the E21G4 protein.

Group 7, claim(s) 13, 14 and 16, drawn to an *in vitro* method of screening or identifying compounds useful in the treatment of diabetes or its complications, obesity or insulin resistance by contacting a test compound with a cell and evaluating the level of E21G4 gene expression.

Art Unit: 1635

Group 8, claim(s) 15, drawn to an *in vitro* method of screening or identifying compounds useful in the treatment of diabetes or its complications, obesity or insulin resistance by contacting a test compound with a cell and evaluating the level of a reporter gene expression.

Group 9, claim(s) 17-19, drawn to an *in vitro* method for the diagnosis or prognosis of diabetes, obesity or insulin resistance by determining the level of expression of a the product of the E21G4 gene.

Group 10, claim(s) 20, drawn to a E21G4 protein monoclonal or polyclonal antibody.

Group 11, claim(s) 21 and 22, drawn to a repressor of the expression of the E21G4 gene which is an antisense.

The inventions listed as Groups 1-11 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups 1-4 lack the same special technical feature because each type of modulator used to manufacture a drug has a different core structure and each modulator acts for different purposes, inhibiting or activating a gene or a protein.

Groups 7-9 lack the same special technical feature because in group 7 the method of screening or identifying compounds is performed by evaluating the level of E21G4 gene expression while in group 8 the method of screening or identifying compounds is performed by evaluating the level of a reporter gene expression and in group 9 E21G4 gene expression level is measured for the purpose of diagnosing or prognosing of diabetes, obesity or insulin resistance.

Groups 1-4 and groups 7-9 lack the same special technical feature because groups 1-4 are directed to modulators of E21G4 while groups 7-9 are directed to methods of screening compound or diagnosing diabetes.

The special technical features of groups 5, 6, 10 and 11 do not make a contribution over the prior art. See Ota et al. (US 7,129,338), who disclose secretory

and membrane proteins, the nucleic acids encoding such proteins, antibodies targeted to these proteins and antisense nucleic acids targeted to the nucleic acids encoding such proteins (see table 1 and columns 6-7). At column 13, Ota et al. disclose that entry "PSEC0170" of table 1 is E21G4.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Conclusion**

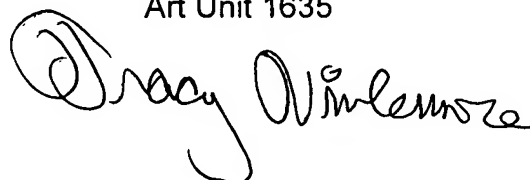
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TV  
June 22, 2007

Tracy Vivlemore  
Examiner  
Art Unit 1635

A handwritten signature in black ink, appearing to read "Tracy Vivlemore", is written over the printed name and title.